K103668

DEC 30 2010

510(k) SUMMARY

This 510(k) Summary for the BNX™ Fine Needle Aspiration System is being submitted in accordance with 21 CFR 807.92.

Submitter's Name and Address:

Boston Endoscopic Engineering (BEE) Corp.
18 Park Street
Danvers, MA USA 01923

Contact Person:

Annette Fagnant, Regulatory Affairs Consultant,
MedDRA Assistance Inc.
53 Kennedy Road
Foster, RI 02825
Phone: 401-392-0287
Fax: 401-397-6531

Date:

November 19, 2010

Name of Medical Device:

Device Regulation: 21 CFR 876.1075, Class II

Product Code: FCG

Common/Usual Name: Kit, Needle, Biopsy (FCG)

Proprietary Name: BNX™ Fine Needle Aspiration System

Classification Panel: Gastroenterology-Urology Devices Panel

Predicate Devices:

The subject device is substantially equivalent to the:

- Cook Medical EchoTip Ultrasound Needle (K083330, cleared 2/6/2009) and
- Olympus Single-Use Aspiration Needle (K023272, cleared 12/23/2002).

Device Description:

The BNX™ Fine Needle Aspiration System is a sterile, single patient use endoscopic ultrasound aspiration needle. The device consists of the BNX™ Aspiration Delivery System and BNX™ Fine Needle Aspiration Needle which are assembled before insertion through the accessory channel of an ultrasound endoscope. The needle is used to acquire aspiration samples from lesions targeted using an ultrasound endoscope. An aspiration sample is obtained by penetrating the lesions with the needle while applying suction. The device will be offered with needle sizes of 19, 22 and 25 gauge.

Indication For Use:

The BNX™ Fine Needle Aspiration System is used to sample targeted sub-mucosal and extramural gastrointestinal lesions through the accessory channel of an ultrasound endoscope.

Technological Characteristics:

The proposed BNX™ Fine Needle Aspiration System has similar intended use and similar technological characteristics compared with the predicate Cook Echo-Tip Ultrasound Needle and the Olympus Single-Use Aspiration Needle. All three devices are endoscopic ultrasound fine needle aspiration (EUS-FNA) biopsy needles designed to be compatible with the accessory channel of standard ultrasonographic endoscopes. A comparison of the intended use of the proposed BNX™ Fine Needle Aspiration System and the predicate devices is provided in the table below. Although the predicate Cook device was cleared for delivery of injectable materials into tissue during endoscopic procedures, similar to the predicate Olympus Single Use Aspiration Needle, the indication for use statement for the for the BNX™ Fine Needle Aspiration System is limited to use for sampling targeted submucosal and extramural lesions within the gastrointestinal tract. The application of an EUS-FNA device for delivery of injectable materials is a separate and distinct use from the procedure required to sample targeted sub-mucosal and extramural gastrointestinal lesions (i.e., no delivery of injectable materials is required for sample acquisition) and therefore exclusion of delivery of injectable materials as a component of the indication statement for the proposed BNX FNA device is not relevant to the safety and effectiveness of the device when used as labeled.

Comparison of Indication for Use Statements		
Proposed Device BNX FNA System (This Submission)	**EchoTip Ultra UltraSound Needle (Cook Medical) K083330**	**Single Use Aspiration Needle (Olympus Medical) K023272**
The BNX™ Fine Needle Aspiration System is used to sample targeted sub-mucosal and extramural gastrointestinal lesions through the accessory channel of an ultrasound endoscope.	This device is intended to be used with an ultrasound endoscope for delivery of injectable materials into tissues during endoscopic procedures and fine needle aspirations (FNA) of submucosal lesions, mediastinal masses, lymph nodes and intraperitoneal masses within or adjacent to the GI tract.	This instrument has been designed to be used with the ultrasound endoscope for ultrasonically guided fine needle aspiration (FNA) of submucosal and extramural lesions within the gastrointestinal tract (i.e. pancreatic masses, mediastinal masses, perirectal masses and lymph nodes).

The referenced EUS-FNA devices incorporate a long stiff metallic needle with stylette housed in a sheath with handle assembly. The handle is screwed onto the luer-lock connection of the endoscope. The needle is manipulated by a handle piston which is locked and unlocked by means of

a screw to avoid advancement of the needle during introduction and withdrawal of the biopsy assembly. The tips of these EUS-FNA needles are etched for enhanced ultrasonic needle visualization. Tissue samples are acquired into the lumen of the needle via applied suction using a standard hypodermic syringe. Whereas, the handle/ sheath/needle sub-assemblies of the predicate Cook and Olympus EUS-FNA are integrated in a single device, the BNX™ FNA System is modular in design, i.e., the sheath and handle assembly are incorporated in a Delivery System as a separate component from the aspiration needle/stylette assembly. The modular design facilitates exchange of any size aspiration needle as the needle can be removed from the scope without requiring that the handle be disconnected.

Performance Data: Biocompatibility and bench testing was performed demonstrating that the subject device is substantially equivalent to the predicate devices for the proposed intended use. Specifically, verification tests were performed on the proposed BNX™ FNA System; including where applicable, a direct comparison with the predicate devices. Verification tests performed included: mechanical/integrity evaluations (i.e., handle tensile strength, handle resistance to torque, bond strengths and needle fracture) and performance evaluations (i.e., device function/durability, aspiration needle/handle locking force, needle and catheter sheath extension locking forces, stylette withdrawal force, perforation testing, needle echogenicity and aspiration capability) both before and following exposure to aging conditions. Additionally, testing has been performed that demonstrates packaging integrity for the labeled shelf-life. Results of performance testing have established that the BNX FNA System is adequately designed for its intended use having established conformance with pre-specified acceptance criteria. Furthermore, the BNX FNA System was determined to be functionally equivalent to the predicate Cook and/or Olympus device with respect to key performance criteria such as needle puncture force and echogenicity (i.e., acoustic reflection). Thus, the performance data verify that the proposed BNX FNA System is substantially equivalent to the currently marketed predicate Cook Medical EUS-FNA device. Based upon testing performed it can be established that BNX FNA System raises no new issues of safety or effectiveness compared with the predicate devices.

Clinical data are not necessary to demonstrate substantial equivalence.

Conclusion: Boston Endoscopic Engineering Corp. has demonstrated that the proposed BNX™ Fine Needle Aspiration System is substantially equivalent to the predicate Cook Echo-Tip Ultrasound Needle and the Olympus Single Use Aspiration Needle.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Boston Endoscopic Engineering Corp.
c/o Paula Wilkerson, RAC
Responsible Third Party Official
Intertek Testing Services NA, Inc.
2307 E. Aurora Road, Unit B7
TWINSBURG OH 44087

DEC 30 2010

Re: K103668
Trade/Device Name: BNX™ Fine Needle Aspiration System
Regulation Number: 21 CFR §876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: FCG
Dated: December 15, 2010
Received: December 16, 2010

Dear Ms. Wilkerson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4.0 Indication for Use Statement

510(k) Number (if known): K103668

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Device Name: BNX™ Fine Needle Aspiration System

Indications for Use:

The BNX™ Fine Needle Aspiration System is used to sample targeted sub-mucosal and extramural lesions of the gastrointestinal tract through the accessory channel of an ultrasound endoscope.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K103668